

NICHD Extramural Associates (EA) Program

EXTRAMURAL ASSOCIATES RESEARCH DEVELOPMENT AWARD (EARDA)... Pilot Project Update

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Web Meeting

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Overview

- Review broadly the updates on policy guidance for EARDA supported pilot research projects
- Respond to questions received in response to a request for questions:
 - Receipt Dates and Budget Periods
 - Development and review of Pilot Research Project Applications
 - Allowable Costs for Travel
 - Data collection at domestic and foreign performance sites
 - Duration of support for pilot project PIs



EARDA Program UPDATES

Pilot Research Projects – Key Dates

- **Letter of Intent:** January 15, 2008; March 15, 2008
- **Application submission/receipt :** February 1, 2008; April 1, 2008
- **Administrative Review:** April/May 2008; June/July 2008
- **Anticipated earliest pilot project start date:** June 2008; August 2008

The letter of intent is not required and is not binding. The information provided will allow the EA Program staff to estimate the potential review workload and plan the administrative review



EARDA Program UPDATES

Pilot Projects

- PIs are encouraged to use PHS Form 398
- Pilot projects should focus on basic biomedical or behavioral research, human subjects research or applied research; have a public health significance; and have relevance to the NIH mission.
- EARDA PIs should submit applications (on behalf of faculty) to their assigned program officials using the email address: nichddsp@mail.nih.gov
- PIs are encouraged to have IRB and IACUC approval as appropriate prior to the submission of pilot research projects.



EARDA Program UPDATES

Review Considerations for Pilot Projects

- **Background**—evidence of literature search that supports the need for the study
- **Significance**
 - Public health significance/implications
 - Project relates to mission of an NIH institute or center
- **Approach**
 - Adequate description of conceptual framework, design, methods, and analyses and appropriateness to the aims
 - Acknowledgement of potential problems / consideration of alternate strategies
- **Innovation**
 - Employment of novel concepts, approaches, methods
 - Originality/use of new technologies



EARDA Program UPDATES

Review Considerations for Pilot Projects (continued)

- **Investigator**
 - Training
 - Expertise in field of study
 - Identification of a mentor
- **Environment**
 - Unique features of the scientific environment
 - Employment of collaborative arrangement with complementary expertise
- **Human Subjects/Animals**
 - Vertebrate animal involvement in research
 - Review by IRB or IACUC as appropriate—provision of results encouraged
 - Gender/recruitment plan
- **Budget**
 - Appropriateness of budget for proposed project
 - Allocation of travel for PI and one student to attend / present at a scientific conference encouraged



Questions/Responses

Q: Rationale for establishing receipt dates for pilot projects on February 1 (and April 1) while the budget years for EARDA grants range from January to December?

R: Ensure that projects are administratively reviewed and approved in time for start dates that coincide with the summer sessions at undergraduate institutions.



Questions/Responses

Q: How can EARDA grantees reconcile the fact that the 12-month budget period for pilot projects will extend beyond the budget year for the EARDA grant?

R: Grantee may carryover funds from one budget period to the next for approved pilot projects only

- All unobligated balances for the budget period must be reported on the Financial Status Report;
- Unobligated funds for an approved pilot project may be noted in the carryover section of the FSR.
- Prior approval to use pilot project funds in the next budget period is not required.
- Carryover of any other unobligated balance requires prior approval and the submission of the required documentation to the grants management specialist



Questions/Responses

Receipt Dates & Budget Periods

Q: Should EARDA PIs anticipate that it will take in excess of one month for grants management to lift the restriction on funds for approved pilot projects?

R: No.

- Grants management will receive notification from Program once all assurances and approvals are in place
- Very little lag time should occur between grant management's receipt of project approvals from Program and sending the **official** pilot project approvals by email to the grantee institution.



Questions/Responses

Receipt Dates & Budget Periods

Q: Is it necessary for EARDA PIs to wait for the new NGA before starting pilot projects that are approved for the upcoming budget year?

R: Yes. Type 5 EARDA awards do not have authority to spend funds outside of the designated budget period.



Questions/Responses

Development and Review of Pilot Research Project Applications

Q: Will Program apply the recommendation from an NIH panel to shorten the length of the [research plan] narrative [in research project applications] from 25 to 7 pages?

R: No. Recommendations must be vetted and approved by the trans-NIH Extramural Policy Committee and a new policy established and disseminated prior to implementation for NIH components.



Questions/Responses

Development and Review of Pilot Research Project Applications

Q: The Extramural Associates Program does not assign scores to pilot research projects that are administratively reviewed for scientific merit. Why?

R: There is not requirement for assigning review scores to pilot projects because there is no competition among the projects for support

- Depending on scientific merit, 100 percent of the pilot projects submitted for administrative review may be supported.

EARDA programs that are unable to carry out their pre-selection process for meritorious pilot projects by the February 1 receipt date should consider submitting their projects for administrative review by the second receipt date—April 1



Questions/Responses

Allowable Costs for Travel

Q: How does the Program plan to address the disparate costs of air travel to scientific meetings for EARDA pilot project PIs and students that reside outside the continental US? The domestic travel allowance for air fare and hotel is \$1,500.

R: With appropriate justification, up to \$ 2000 may be requested for air travel and hotel for a pilot project PI and student residing outside the continental US to attend a scientific meeting.



Questions/Responses

Data Collection at Foreign Performance Sites

Q: Can data be collected in a foreign country if the research does not involve testing [in] human subjects?

R: No. Data collection at foreign performance sites is not allowable under the G11 grant mechanism.

- More generally in regard to NIH grant mechanisms that support research at foreign performance sites (i.e., R01, etc), the inclusion of a foreign performance site can only be justified if the research involves a foreign population, collection of non-domestic animal specimens, or the use of instrumentation not available domestically.



Questions/Responses

Duration of Support for Pilot Projects

Q: What is the maximum period of support for pilot project PIs under the EARDA grant award?

R: Starting in 2008, programs funded under PAR-05-053, with two or more years remaining on the 5-year grant award, may at their discretion, fund NEW pilot projects for 1-year and/or 2-year project periods.

- Awards for pilot projects reviewed and approved for two years of support are not renewable. This means that a faculty member may compete for only two years of pilot project support during the 5-year EARDA project period, without prior approval from the Extramural Associates Program.
- PIs of pilot projects reviewed and approved for a 1-year project period may compete for an additional year of support for the same or a different project during the 5-year EARDA project period, without prior approval from the Extramural Associates program.



Questions/Responses

Duration of Support for Pilot Projects

(Continued)

The policy on the length of support for EARDA pilot projects reflects three considerations:

Pilot research projects differ in terms of the time required to collect and analyze data;

- Pilot projects are currently reviewed for scientific merit; and pending applicability, for compliance with regulatory guidance on human subjects and the care and use of animals in research as required; and
- Pilot project support is intended to enable faculty to use the preliminary data to garner research support for an expanded research project using the NIH small grant (R03) or Academic Research Enhancement Award (AREA) grant (R15) mechanisms or related mechanisms from other funding agencies.

Should the EARDA PI successfully compete for a competitive renewal grant award, a previous awardee of pilot project funds would again be eligible to compete at his/her institution for EARDA pilot project support.



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